trials had a highly selected population of diabetic patients, which may not be representative of the risk for cardiovascular events in the general diabetic population.

Perhaps more importantly, the method for development of AUC is rigorous and does not permit alteration of the final scores and classification by the technical (rating) panel. Additionally, the AUC do not state that testing "must" be performed, only that it is reasonable given the clinical scenario and the available medical knowledge/experience. AUC are therefore not equivalent to a Class I clinical practice guideline.

Although the COURAGE nuclear substudy was underpowered to detect differences in treatment approaches, those subjects who experienced a reduction of ischemia on single-positron emission computed tomography myocardial perfusion imaging had a superior outcome, although this difference was lost when further risk adjusted. Therefore, we agree with the opinion of Dr. Sethi and colleagues that "routine RNI can be of use, if we can identify a subgroup of asymptomatic patients . . . who can benefit from revascularization." This thereby allows the indication to be considered "appropriate" or reasonable in the parlance of AUC.

We agree that, in light of the newer trials, it may not be accurate to place patients with only the risk factor of diabetes into the high-risk category. However, based on available information, we believe that the rating by the technical panel was reasonable. We await additional information on the best way for risk assessment of patients and will certainly consider revising the AUC as new evidence becomes available. Thank you for your thoughtful comments.

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The Need for Sex-Specific Data Prior to Food and Drug Adminstration Approval

We read with great interest the recent paper by Hsich and Piña (1) that examined the many aspects in which we lack data for heart failure in women. We wholeheartedly agree that heart failure trials must include more women and must provide more sex-specific data, and we further believe that there must be evidence of net benefit in women before Food and Drug Administration approval for devices to be implanted in critically ill patients.

For example, the authors mention that the recent approval of the Thoratec HeartMate II (Thoratec Corporation, Pleasanton, California) will allow more implantation of ventricular assist devices in women and will provide prospective data through the Interagency Registry for Mechanically Assisted Circulation registry. However, the device was approved based on data from only 44 women, who constituted 23% of the overall study population. The Food and Drug Administration's Summary of Safety and Effectiveness Data for this device noted that the small number of women "makes it difficult to draw any conclusions regarding differences in safety profile of the device between men and women" (2). Even so, it is worrisome that women had an increased rate of some important adverse events, including a 3-fold higher incidence of stroke (18% vs. 6% in men) and trends toward a higher incidence of bleeding and infection events. These risks may be worthwhile if the device had proven benefit, but it is concerning that the device's success rate did not meet the pre-specified end point for success (2).

Therefore, we agree with the authors that a post-approval registry to collect data on outcomes in women for this device will provide needed information. However, requiring evidence of benefit in women before Food and Drug Administration approval for implanted devices would be an important step toward ensuring that we are providing safe care for women with heart failure.

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Reply

We appreciate the insightful remarks of Drs. Dhruva and Redberg on our paper (1). We agree that to improve health care for women,